CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENTS OF INTELLECTUAL PROPERTY REGULATIONS FOR FOR-PROFIT ORGANIZATIONS – SECTIONS 100407 AND 100408

HEARING DATE: None scheduled.

SUBJECT MATTER OF PROPOSED AMENDMENTS: Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations – Revenue Sharing and Access Requirements for Grantees

SECTIONS AFFECTED: The proposed amendments apply to Chapter 4 and sections 100407 and 100408 of Title 17 of the California Code of Regulations.

SECTION 100407. ACCESS REQUIREMENTS FOR PRODUCTS DEVELOPED BY FOR-PROFIT GRANTEES.

Purpose:

The purpose of this section is to make the grantee aware of its obligation to provide at the time of commercialization a plan to CIRM that provides access to resultant therapies for uninsured Californians. The access plan must be consistent with industry standards existing at the time of commercialization, which plans may be reviewed by the ICOC and will be made available to the public.

Grantees also are required to provide drugs purchased in California with public funds at a discount price. Grantees agree to provide drugs purchased in California with public funds at a benchmark price identified in the California Discount Prescription Drug Program.

Subdivision (a) states that a grantee (or, by terms of an Exclusive License, its exclusive licensee) must submit a plan to afford uninsured Californians access to a Drug, as defined in Title 17, California Code of Regulations, section 100401, subdivision (e), the development of which was in whole or in part the result of CIRM-funded Research. (1) A Grantee must submit this access plan to CIRM at the time the Drug is commercialized; (2) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee or its exclusive licensee; (3) CIRM will review the access plan and may make it available for review by the ICOC and the public; (4) The Grantee or its exclusive licensee is responsible only for providing the Drug itself, not any costs of administering the Drug or other attendant care.

The proposed amendments require submission of an access plan to CIRM prior to the time the Drug is commercialized (a)(1), and state the plan is subject to CIRM's approval after a public hearing and opportunity for public comment (a)(3).

Subdivision (b) states that a Grantee (or its exclusive licensee) must provide a Drug, the development of which was in whole or in part the result of CIRM-funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under this program.

The proposed amendment to subdivision (b) states that the pricing provisions of the CDPDP on the last day it is in effect will apply if the program is repealed.

Subdivision (c) states that A Grantee or its exclusive licensee must sell a Drug, the development of which is in whole or in part the result of CIRM-funded Research, and which is purchased in California with public funds (as defined in Title 17, California Code of Regulations, section 100401, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

The proposed amendment to subdivision (c) states that the pricing provisions of the CDPDP on the last day it is in effect will apply if the program is repealed.

Rationale:

As a consequence of expenditure of the "first dollar" of CIRM funding, the for-profit grantee agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. The access plan shall be consistent with industry standards extant at the time of commercialization. This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California's taxpayers.

Access plans comprise one of three components of our regulations concerning access to Californians. The first is to require Grantees or their exclusive licensees to submit a plan to CIRM to afford uninsured Californians access to a Drug. The second requires Grantees or their exclusive licensees to participate in the CalRx Discount Prescription Drug Program (or a later iteration) for discounts to drugs. The third component requires Grantees or their exclusive licensee to provide drugs at the benchmark prices described in the CalRx program (or a later iteration) to entities that purchase drugs with public funds.

The language of subdivision (a) was developed with the knowledge that we cannot predict what a drug or therapy will be and therefore cannot prescribe at this point in time what the particulars of such an access plan would look like. Moreover, the economics of treatments and therapies for orphan diseases are typically vastly different from more major or common chronic diseases, and this also has a significant effect on the model and particulars of a given type of access plan, making it all the more difficult to prescribe. The goal is to ensure, nevertheless, that whatever is proposed is typical for that drug or therapy.

In addition, the awardees will provide the therapies at a discount price to residents whose therapies are purchased in California by public funds. For drugs generated as a consequence of CIRM funding, grantees agree to provide drugs at benchmarks described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) to eligible Californians under that program.

The amendments to subdivision (a) will clarify the opportunity for CIRM review of access plans when a Drug is commercialized. The amendments to subdivisions (b) and (c) propose to maintain the CDPDP benchmarks in the event the CDPDP is repealed.

SECTION 100408. REVENUE SHARING

Purpose:

This section describes the requirements of grantees with respect to the sharing of revenues obtained by licensing and developing CIRM-funded inventions.

Subdivision (b) describes the rules for revenue sharing that pertain from self-commercialized products that result from CRIM-funded Research.

Subpart (1) states that a grantee must pay royalties to the state on Net Commercial Revenue exceeding the threshold amount described in subdivision (a)(1), not to exceed three times the total amount of the CIRM grant or grants. The rate of payback in the form of a royalty shall be negotiated between the Grantee and the CIRM, within the described range of 2 percent and 5 percent of the annual Net Commercial Revenue from the invention, except as described further in the event of "blockbuster status."

Subpart (2) states that if Net Commercial Revenue exceeds the milestone of $250 million per year from a self-commercialized CIRM-funded Patented Invention, and then if Net Commercial Revenue exceeds the milestone of $500 million per year from a self-commercialized CIRM-funded Patented Invention, then upon the first occurrence of each of these milestones the Grantee will pay to the State of California a one-time blockbuster payment of three times the total amount of the Grant.

Subpart (3) states that if CIRM has invested more than $5 million in the research project AND a CIRM-funded patented invention was involved in the achievement of Net Commercial Revenues equal to or greater $500 million per year, CIRM requires payment of 1 percent of Net Commercial Revenues in excess of $500 million for the life of the patents. This additional royalty payment is on top of any other payments due under the other provisions of this regulation.

The proposed amendment to subdivision Subpart (2) deletes reference to a CIRM-funded Patented Invention and replaces it with the reference to products resulting from CIRM-funded Research.

Rationale:

Self-Commercialization:

For-profit research organizations are structured to develop products for public benefit according to their research interests and business plans. As a consequence of this, it is likely that some CIRM for-profit grantees will intend to develop CIRM-funded projects for their own use rather than licensing rights to them to third parties. After extensive research, CIRM has developed proposed revenue sharing strategies to provide appropriate options in the best interests of the State of California.

Awards to for-profit research organizations will be accompanied by specific agreements that describe payment expectations and time periods under which payments must be made. Such agreements will be individually negotiated with the aim of ensuring that companies are not subject to undue risk as a consequence of payment schedules. In the negotiation of these agreements, CIRM recognizes that the selection of an appropriate royalty rate is required to successfully balance the expectation of the State of California for remuneration with the specific circumstances of the business position of the company. CIRM will use as its guide a royalty range of 2 to 5 percent as it negotiates the payment schedule for the expected capped return.

For grants made to for-profit organizations, the State of California will expect a return only in the event of successful commercialization of a product that stems from a CIRM-funded research project. Success will be defined as the receipt of revenues in excess of $500,000 from the CIRM-funded research-enabled product. In such cases, the State of California will receive up to three times the amount received under CIRM funding in the form of a capped royalty. For example, if CIRM awarded a $1 million grant that ultimately gave rise to a product that generates revenue, the State of California is expected to receive of up to a total of $3 million in royalty payments. The payment schedule will be negotiated using a royalty range of 2 to 5 percent to determine the rate at which the threefold return will be recovered.

The proposed amendments provide clarification as to when the payments are due under Subpart (b)(2). As stated in the introductory language of subdivision (b) and in (b)(1), the payments in that section are due regardless of whether a CIRM-funded Patented Invention is involved. The amendments clarify the intent that Subpart (b)(2) also applies regardless of whether a CIRM-funded Patented Invention is involved by substituting the same language as used in Subdivision (b). Thus, for grants that lead to very successful commercial products from a self-commercialized product resulting from its CIRM-funded Research, additional one-time blockbuster payments equal to three times the amount provided by CIRM is expected when revenues exceed $250 million per year and when revenues exceed $500 million per year.

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